



## Post Authorisation Assessments

### Furosemide Tablets BP (Vet) 20 mg

Vm 61300/3000

28 August 2025	Change of legal entity of the Marketing Authorisation Holder from Millpledge Ltd, Whinleys Estate, Clarborough, Retford, Nottinghamshire, DN22 9NA to Millpledge Europe BVBA, 38 Verrekijker, 8750 Wingene, Belgium.
18 January 2025	Deletion of a non-significant specification parameter for the finished product.
18 May 2024	Reduction in the testing frequency of an analysis, from routine testing to skip or periodic testing.
21 December 2022	Addition of microbiological testing site.
06 December 2022	Change in the name or address or contact details of a qualified person for pharmacovigilance.
31 August 2022	Change in the specification limits for dissolution of the finished product. Change in assay specification limits testing method. Changes in the related substances specification. Replacement of a batch release testing site for a finished product. Addition of a batch release site.
18 May 2022	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
22 April 2021	Change in storage conditions of the finished product.
18 March 2021	Addition of a new specification parameter to the specification with its corresponding test method of the finished product. Update of the dossier to comply with the provisions of an updated general monograph of the Ph. Eur for the finished product. Change in the specification parameters and/or limits of the finished product. Addition of new tests and limits applied during the manufacture of the finished product. Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.
03 November 2020	Change in the QPPV of an existing pharmacovigilance system as described in the DDPS. Change in the QPPV of an existing pharmacovigilance system as described in the DDPS.
28 January 2020	An update to amend the source of a supplier of an excipient.
14 January 2020	Change in the safety database of an existing pharmacovigilance system as described in the DDPS.
02 January 2020	Tightening of in-process limits applied during the manufacture of the finished product. Tightening of specification limits of the finished product. Addition of a new specification parameter to the specification with its corresponding test method of the finished product.

	<p>Addition of a site where batch control/testing takes place.</p> <p>Deletion of manufacturing site for an active substance.</p> <p>Deletion of manufacturing site for finished product.</p> <p>Submission of an updated Ph. Eur. certificate of suitability for an active substance from an already approved manufacturer.</p>
02 January 2020	<p>Tightening of specification limits of the finished product.</p> <p>Tightening of in-process limits applied during the manufacture of the finished product.</p>
06 July 2018	<p>Change in the name of a manufacturer of active substance used in the manufacture of the active substance.</p> <p>Replacement of a site where batch control/testing takes place.</p>
29 October 2010	<p>Addition of a manufacturing site for testing of dosage form</p>
24 March 2009	<p>Addition of a manufacturing site for all of the manufacturing process of the finished product</p>
19 December 2008	<p>Introduction of a new label type</p>
19 November 2008	<p>Change or addition of imprints, bossing or other markings (except scoring/break lines) on tablets or printing on capsules, including replacement, or addition of inks used for product marking.</p>
16 November 2006	<p>Changes to the SPC and Product Literature to bring in line with new legislation</p>
31 March 2006	<p>Renewal</p>
14 October 2004	<p>Change of name of product from 'Frusemide Tablets BP 20mg' to 'Furosemide Tablets BP (Vet) 20mg'</p>
16 April 2004	<p>Addition of a manufacturing site for the finished product</p>
31 January 2003	<p>Addition of a manufacturer of the active substance</p>
08 November 2002	<p>Change of specification of the finished product</p>
30 November 1999	<p>Addition of a manufacturer of the active substance</p>